



DEPARTMENT OF VETERANS AFFAIRS

8320-01

38 CFR Part 17

RIN 2900-AP73

Release of VA Records Relating to HIV

AGENCY: Department of Veterans Affairs.

ACTION: Proposed rule.

SUMMARY: The Department of Veterans Affairs (VA) proposes to amend its medical regulations governing the release of VA medical records. Specifically, VA proposes to eliminate the restriction on protecting a negative test result for the human immunodeficiency virus (HIV). HIV testing is a common practice today in healthcare and the stigma of testing that may have been seen in the 1980s when HIV was first discovered is no longer prevalent. Continuing to protect negative HIV tests causes delays and an unnecessary burden to veterans when VA tries to share electronic medical information with the veterans' outside providers for their treatment through health information exchange efforts. For this same reason, VA would also eliminate negative test results of sickle cell anemia as protected medical information. This proposed rule would eliminate the current barriers to electronic medical information exchange.

DATES: Comments must be received on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Written comments may be submitted through www.Regulations.gov; by mail or hand-delivery to Director, Regulation Policy and Management (00REG), Department of Veterans Affairs, 810 Vermont Avenue, NW, Room 1068, Washington, DC 20420; or by fax to (202) 273-9026. Comments should indicate that they are submitted in response to “RIN 2900-AP73– Release of VA Records Relating to HIV.” Copies of comments received will be available for public inspection in the Office of Regulation Policy and Management, Room 1068, between the hours of 8 a.m. and 4:30 p.m., Monday through Friday (except holidays). Please call (202) 461-4902 for an appointment. (This is not a toll-free number.) In addition, during the comment period, comments may be viewed online through the Federal Docket Management System at www.Regulations.gov.

FOR FURTHER INFORMATION CONTACT: Stephania H. Griffin, Director, Information Access and Privacy Office (10P2C), Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420; (704) 245-2492. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: The Veterans Omnibus Health Care Act of 1976, Public Law 94-581, codified at 38 U.S.C. 7332, ensured confidentiality of medical records relating to drug abuse, alcoholism, and sickle cell anemia by establishing sanctions for unauthorized disclosure of information while meeting the legitimate needs for disclosure under certain conditions. In 1988, Public Law 100-322 added to this list the confidentiality of medical records relating to infection with the human immunodeficiency virus (HIV). Section 7332 states that records of the identity,

diagnosis, prognosis, or treatment of any patient or subject which are maintained in connection with the performance of any program or activity (including education, training, treatment, rehabilitation, or research) of any patient or subject relating to drug abuse, alcoholism or alcohol abuse, infection with the human immunodeficiency virus (HIV), or sickle cell anemia shall only be disclosed under certain circumstances. The intent of section 7332 is to protect the medical records of those veterans who are undergoing treatment or have a positive diagnosis for the conditions stated in this section. Due to the stigma associated with HIV and HIV testing at the time, VA determined that the results of HIV testing should be protected regardless of the outcome of the test. However, HIV testing is common practice today. In the past, VA required health care providers to counsel patients as part of the informed consent process prior to ordering HIV testing. Currently, HIV testing is considered part of routine health care under VA policy, similar to other types of diagnostic laboratory testing, and while oral informed consent is still required no pre-testing counseling is required.

The continued protection of negative HIV tests has posed significant obstacles to the sharing of medical information between VA and non-VA medical providers, and also places an undue burden on veterans. If VA conducts an HIV test on a veteran, VA is prevented from electronically disclosing the veteran's medical information to the veteran's non-VA medical provider, even if the test result is negative, unless VA first obtains a specific written authorization that meets title 38 regulatory requirements from the veteran to share the medical information. Medical information sharing is crucial to treating a veteran who has outside medical providers and is significant in making certain

that a veteran is not prescribed a medication that may negatively interact with other medications. Under section 7332, sickle cell anemia is also considered protected medical information. As with negative HIV test results, the prohibition on sharing negative test results for sickle cell anemia has posed challenges for the timely provision of medical care. This rulemaking would eliminate the current restrictions on sharing negative test results of veterans for HIV and sickle cell anemia and would be in line with the intent of the statute. As for positive HIV or sickle cell anemia test results, VA would continue to require a qualifying written authorization from the veteran prior to disclosure of such information.

Section 1.460 Definitions

Section 1.460 defines terms that apply to §§ 1.460 through 1.499, which cover the release of information from VA records relating to drug abuse, alcoholism or alcohol abuse, infection with HIV, or sickle cell anemia. The term “HIV” is defined as the presence of laboratory evidence for human immunodeficiency virus infection. The definition for “HIV” also states that “[f]or the purposes of §§ 1.460 through 1.499 of this part, the term includes the testing of an individual for the presence of the virus or antibodies to the virus and information related to such testing (including tests with negative results).” We propose to modify this definition because VA would only restrict the release of health information for positive results. The proposed definition would define “HIV” to mean “the presence of laboratory evidence for human immunodeficiency virus infection. The term does not include negative results from the testing of an individual for the presence of the virus or antibodies to the virus, or such testing of an

individual where the results are negative.” As previously stated in this rulemaking, negative results are not protected under this provision.

The term “patient” is defined in part in § 1.460 to state that it includes an individual or subject who is tested for infection with HIV or sickle cell anemia. We propose to amend this definition to state that the term ‘patient’ for purpose of infection with the human immune deficiency virus or sickle cell anemia, includes one tested positive for the disease even if no treatment is provided. The term does not include a patient who has tested negative for the disease. We would make this amendment to clarify that VA would only protect the medical information of a patient who tested positive for HIV or sickle cell anemia and not all individuals who were tested for these diseases. Although section 7332 considers sickle cell anemia as protected health information, it is silent on the protection of a negative test for sickle cell anemia. We would treat an individual who tested negative for sickle cell anemia in the same manner as an individual who tested negative for HIV. For this same reason, we propose to modify the last sentence in the definition of the term “treatment” to state the term does not include testing for the human immunodeficiency virus or sickle cell anemia where the results of such tests are negative. We would also amend the definition of “treatment” by stating that “treatment” means the diagnosis, management and care of a patient for infection with the human immunodeficiency virus or sickle cell anemia. This proposed addition would clarify what VA considers 7332-protected medical information.

Section 1.461 Applicability

Paragraph (a)(1)(i) of 38 CFR 1.461 states the restrictions on disclosure of medical information, specifically information that would identify a patient as an alcohol or drug abuser, an individual tested for or infected with the human immunodeficiency virus (HIV), hereafter referred to as HIV, or an individual with sickle cell anemia, either directly, by reference to other publicly available information, or through verification of such an identification by another person. As previously stated in this rulemaking, we would no longer consider 7332-protected medical information to include a negative test for HIV or sickle cell anemia. Therefore, we propose to amend § 1.461(a)(1)(i) by removing the restriction on disclosure of medical information for an individual who has tested negative for HIV or sickle cell anemia. Paragraph (a)(1)(i) would only protect medical information for individuals who have tested positive for or are infected with HIV, or have tested positive for or have sickle cell anemia.

Effect of Rulemaking

The Code of Federal Regulations, as proposed to be revised by this proposed rulemaking, would represent the exclusive legal authority on this subject. No contrary rules or procedures would be authorized. All VA guidance would be read to conform with this proposed rulemaking if possible or, if not possible, such guidance would be superseded by this rulemaking.

Paperwork Reduction Act

This proposed rule contains no provisions constituting a collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3521).

Regulatory Flexibility Act

The Secretary hereby certifies that this proposed rule would not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act, 5 U.S.C. 601-612. This proposed rule would directly affect only individuals and would not directly affect small entities. Therefore, pursuant to 5 U.S.C. 605(b), this rulemaking would be exempt from the initial and final regulatory flexibility analysis requirements of 5 U.S.C. 603 and 604.

Executive Order 12866 and 13563

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, and other advantages; distributive impacts; and equity). Executive Order 13563 (Improving Regulation and Regulatory Review) emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. Executive Order 12866 (Regulatory Planning and Review) defines a “significant regulatory action,” requiring review by the Office of Management and Budget (OMB), unless OMB waives such review, as “any regulatory action that is likely to result in a rule that may: (1) Have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) Create a serious

inconsistency or otherwise interfere with an action taken or planned by another agency; (3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive Order."

The economic, interagency, budgetary, legal, and policy implications of this regulatory action have been examined, and it has been determined not to be a significant regulatory action under Executive Order 12866. VA's impact analysis can be found as a supporting document at <http://www.regulations.gov>, usually within 48 hours after the rulemaking document is published. Additionally, a copy of the rulemaking and its impact analysis are available on VA's Web site at <http://www.va.gov/orpm/>, by following the link for "VA Regulations Published From FY 2004 Through Fiscal Year to Date."

Unfunded Mandates

The Unfunded Mandates Reform Act of 1995 requires, at 2 U.S.C. 1532, that agencies prepare an assessment of anticipated costs and benefits before issuing any rule that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100 million or more (adjusted annually for inflation) in any one year. This proposed rule would have no such effect on State, local, and tribal governments, or on the private sector.

Catalog of Federal Domestic Assistance

The Catalog of Federal Domestic Assistance numbers and titles for the programs affected by this document are 64.007, Blind Rehabilitation Centers; 64.008, Veterans Domiciliary Care; 64.009, Veterans Medical Care Benefits; 64.010, Veterans Nursing Home Care; 64.011, Veterans Dental Care; 64.012, Veterans Prescription Service; 64.014, Veterans State Domiciliary Care; 64.015, Veterans State Nursing Home Care; 64.018, Sharing Specialized Medical Resources; 64.019, Veterans Rehabilitation Alcohol and Drug Dependence; 64.022, Veterans Home Based Primary Care; and 64.024, VA Homeless Providers Grant and Per Diem Program.

Signing Authority

The Secretary of Veterans Affairs, or designee, approved this document and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs. Gina S. Farrisee, Deputy Chief of Staff, Department of Veterans Affairs, approved this document on August 1, 2016, for publication.

List of Subjects in 38 CFR Part 1

Administrative practice and procedure, Archives and records, Cemeteries, Claims, Courts, Crime, Flags, Freedom of information, Government contracts, Government employees, Government property, Infants and children, Inventions and patents, Parking, Penalties, Postal Service, Privacy, Reporting and recordkeeping requirements, Seals and insignia, Security measures, Wages.

Dated: August 2, 2016.

Janet J. Coleman
Chief
Office of Regulation Policy & Management,
Office of the Secretary,
Department of Veterans Affairs.

For the reasons set out in the preamble, Department of Veterans Affairs proposes to amend 38 CFR part 1 as follows:

PART 1 – GENERAL PROVISIONS

1. The authority citation for part 1 continues to read as follows:

AUTHORITY: 38 U.S.C. 501(a), and as noted in specific sections.

2. Amend § 1.460 by:

- a. Revising the last sentence of the definition of “Infection with the human immunodeficiency virus (HIV).”

- b. Revising the definition of “Patient.”

- c. Revising the definition of “Treatment.”

The revisions read as follows:

§ 1.460 Definitions.

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Infection with the human immunodeficiency virus (HIV). * * * The term does not include negative results from the testing of an individual for the presence of the virus or antibodies to the virus, or such testing of an individual where the results are negative.

* * * * *

Patient. The term “patient” means any individual or subject who has been given a diagnosis or treatment for drug abuse, alcoholism or alcohol abuse, infection with the human immunodeficiency virus, or sickle cell anemia and includes any individual who, after arrest on a criminal charge, is interviewed and/or tested in connection with drug abuse, alcoholism or alcohol abuse, infection with the human immunodeficiency virus, or sickle cell anemia in order to determine that individual's eligibility to participate in a treatment or rehabilitation program if the result of such testing is positive. The term “patient” includes an individual who has been diagnosed or treated for alcoholism, drug abuse, HIV infection, or sickle cell anemia for purposes of participation in a VA program or activity relating to those four conditions, including a program or activity consisting of treatment, rehabilitation, education, training, evaluation, or research. For the purpose of infection with the human immunodeficiency virus or sickle cell anemia, the term “patient” includes one tested positive for the disease even if no treatment is provided, offered, or requested. The term does not include a patient who has tested negative for the disease.

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Treatment. The term “treatment” means the management and care of a patient for drug abuse, alcoholism or alcohol abuse, or the diagnosis, management and care of a patient for infection with the human immunodeficiency virus, or sickle cell anemia, or a condition which is identified as having been caused by one or more of these conditions, in order to reduce or eliminate the adverse effects upon the patient. The term does not

include negative test results for the human immunodeficiency virus, antibodies to the virus, or sickle cell anemia, or such testing of an individual where the results are negative.”

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3. Revising § 1.461(a)(1)(i) to read as follows.

§1.461 Applicability.

(a) * * *

(1)* * *

(i) Would identify a patient as an alcohol or drug abuser, an individual who tested positive for or is infected with the human immunodeficiency virus (HIV), hereafter referred to as HIV, or an individual who tested positive for or has sickle cell anemia, either directly, by reference to other publicly available information, or through verification of such an identification by another person; and

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